IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Bernd RIEDL et al.

Serial No.: 09/889,227 Group Art Unit: 1625

Filed: January 8, 2002 Examiner: Rita J. Desai

For: Ω-CARBOXYARYL SUBSTITUTED DIPHENYL UREAS AS RAF KINASE INHIBITORS

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:

- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
- ☐ within three months of the actual filing date of the national phase of a PCT application; OR
- ☒ before the mailing of a first substantive office action (including after filing of an RCE).

☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:

a final rejection under 37 C.F.R. 1.113;
termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

☐ a check covering the fee of $180.00 under 37 C.F.R. § 1.17(p).

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☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);

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Statements Under 37 C.F.R. 1.97(e)

☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or

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Cited Materials

☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).

☐ Copies of materials listed but not attached were cited in an international search report dated _____.

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Non-English Language References

☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
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E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
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☐ Translation of other relevant information on foreign search report

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Other Information

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☐ A check for $_____ covering the fee identified above is attached.

☐ Please charge to Deposit Account No. 13-3402 $_____ for the fee identified above.

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Respectfully submitted,

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Attorney Docket No.: BAYER-0015-A

Date: May 24, 2006

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 10

Complete if Known	
Application Number	09/889,227
Filing Date	January 8, 2002
First Named Inventor	Bernd RIEDL et al.
Group Art Unit	1625
Examiner Name	Rita J. Desai
Attorney Docket Number	BAYER-0015-A

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	A1	2002/0173507	A1	Santora et al.	11-21-2002
	A2	2002/0065283	A1	McMahon et al.	05-30-2002
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	A14	6358945	B1	Breitfelder et al.	03-19-2002
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	A20	3284433		Becker et al.	11-08-1986
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	B1	WO	02/14311	A2	Amgen Inc.	02-21-2002		
	B2	WO	02/32872	A1	Eisai Co. Ltd.	04-25-2002		
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	B5	WO	01/04115	A2	Boehringer Ingelheim	01-18-2001		
	B6	WO	99/82890	A1	Pfizer Products Inc.	12-09-1999		

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	B7	JP	01200254	A2	Hirabayashi Shigeto	08-11-1989		
	B8	JP	01102461	A2	Hirabayashi Shigeto	04-20-1989		
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	B19	WO	00/50425	A1	Boehringer Ingelheim	08-31-2000		
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	B23	WO	2005/048948	A2	Ambit Biosciences	06-02-2005		
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Attorney Docket Number	BAYER-0015-A

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	B34	WO	01/07411	A1	Banyu Pharmaceutical	02-01-2001		
	B35	UK	1110099		Julia	06-07-1968		
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	B60	WO	0214281	A1	Cochran et al.	02-21-2002		
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	B79	WO	9928305	A1	Walker	06-10-1999		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	C1	Nickel et al., "Carboxylic acid analogues of suramin, potential filaricides," *Indian Journal of Chemistry*, Vol. 30B, February 1991, p. 182-187	
	C2	Duam et al., "The ins and outs of Raf kinases," TIBS 19, November 1994, p. 474-480.	
	C3	Campbell et al., "Increasing complexity of Ras signaling," *Oncogene*, (1998) 17, 1395-1413	
	C4	Bolton et al., "Ras oncogene directed approaches in cancer chemotherapy," *Annual Reports in Medicinal Chemistry*, 29, pp. 165-174	
	C5	Moelling et al., "Signal transuction as target of gene therapy," Institute of Medical Virology, University of Zürich, *Recent Results in Cancer Research*, Vol. 142, pp. 63-71	

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	C6	Jay H. Stain, Internal Medicine, 4th Edition, 1994, pp. 699-715	
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	C9	Lyons et al., "Discovery of a novel Raf kinase inhibitor," *Endocrine-Related Cancer*, (2001) 8, 219-225	
	C10	Lowinger et al., "Design and discovery of small molecules targeting Raf-1 kinase," *Current Pharmaceutical Design*, 2002, 8, 2269-2278	
	C11	Dumas et al., "Recent developments in the discovery of protein kinase inhibitors from the urea class," *Current Opinion in Drug Discovery & Development*, 2004, 7(5):800-616	
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	C14	Hotte et al., "BAY 43-9006: Early Clinical Data in Patients with Advanced Solid Malignancies," *Current Pharmaceutical Design*, 2002, 8, 2249-2253	
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	C18	Wilhelm et al., "BAY 43-9006 Exhibits broad spectrum oral antitumor activity and targets the RAF/MEK/ERK pathway and receptor tyrosine kinases involved in tumor progression and angiogenesis," *Cancer Research*,. 64, 7099-7109, October 1, 2004	
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	C20	Bankston et al., "A scaleable synthesis of BAY 43-9006: a potent raf kinase inhibitor for the treatment of cancer," *Organic Process Research & Development*, 2002, 8, 777-781	

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	C21	Strumberg et al., "Results of phase I pharmacokinetic and pharmacodynamic studias of the raf kinase inhibitor BAY 43-9006 in patients with solid tumors," *International Journal of Clinical Pharmacology and Therapeutics*, Vol. 40, No. 12/2002 (580-581)	
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	C23	Panka et al., "BAY 43-9008 induces apoptosis in melanoma cell lines," 96th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	
	C24	Auclair, et al., "BAY 43-9006 (Sorafenib) is a potent inhibitor of FLT3 tyrosine kinase signaling and proliferation in AML cells," 96th Annual Meeting, April 16-20, 2005, Anaheim/Orange County, CA	
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	C26	Spronsen et al., "Noval treatment strategies in clear-cell metastatic renal cell carcinoma," *Anti-Cancer Drugs*, 2005, 16:709-717	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 7 of 10

Complete if Known	
Application Number	09/889,227
Filing Date	January 8, 2002
First Named Inventor	Bernd RIEDL et al.
Group Art Unit	1625
Examiner Name	Rita J. Desai
Attorney Docket Number	BAYER-0015-A

NON PATENT LITERATURE DOCUMENTS (cont'd.)

Examiner Initials *	Cite No [1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T [2]
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